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REMARKS

Claims 36 and 69 have been amended. Claims 51-66 have been withdrawn from consideration as being directed to non-elected inventions. Thus, claims 36-69 are pending in the present application, with claims 36-50 and 67-69 currently under consideration. Support for the amendment to claim 36 may be found in the specification at page 3, lines 17-23; page 6, lines 6-18; page 8, lines 13-15 and 22-25; and in the Examples. Thus, no new matter has been added. Reconsideration and withdrawal of the present objection and rejections in view of the remarks presented herein are respectfully requested.

Rejection under 35 U.S.C. § 102(b)

Claims 36-41, 46 and 47 were rejected under 35 U.S.C. § 102(b) as being anticipated by Zhao (WO 00/46253). The Examiner alleges that Zhao teaches a method for producing a cross-linked gel wherein an alkaline solution of hyaluronic acid (HA) in sodium hydroxide is mixed with varied volumes of the epoxide 1,2,7,8-diepoxyoctane, drying the mixture into a gel formation, purifying (i.e., washing) the dried gel using acetone/water, acetone/isopropyl alcohol, and neutralising the gel in an acidic medium of acetone/hydrochloric acid at pH 5. The Examiner also contends that Zhao teaches additional cross-linking agents such as butanediol diglycidyl ether.

Claim 36 as amended recites a process for preparing a cross-linked polysaccharide gel that is substantially resistant to degradation and wherein the cross-linked polysaccharide gel has a single type of cross-linkage

In order for a reference to anticipate a claim, all elements of the claim must be found within the reference. Zhao does not disclose all of the process steps recited in the present claims. In particular, Zhao discloses a process for forming multiple cross-linkages of HA or its derivatives with two or more different types of cross-linking bonds. This is evident from claim 1 of Zhao, which recites cross-linking HA with two or more different functional groups. Throughout the specification, Zhao emphasizes the formation of HA cross-linked by two or more different types of bonds (see, for example, page 4, lines 13-25; page 12, line 26 to page 13, line 1). In addition, the processes described in the Examples of Zhao result in a double cross-linked HA gel (see page 24, lines 10-12).

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Thus, Zhao does not teach (or suggest) a process for preparing a cross-linked polysaccharide gel that is substantially resistant to degradation and wherein the cross-linked polysaccharide gel has a single type of cross-linkage as presently claimed. Thus, claims 36-41, 46 and 47 cannot be anticipated by this reference.

In view of the comments presented above, Applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. § 102(b).

Rejection under 35 U.S.C. § 103(a)

Claims 36-50 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Zhao (WO 00/46253) in view of Mälson (WO 87/07898). The Examiner alleges that it would be obvious to modify the gel-producing method of Zhao with the freeze-drying gel preparation step taught by Mälson since the combined teachings disclose the instantly claimed method for producing a biologically active cross-linked gel composition. The Examiner also contends that the combination of Zhao and Mälson discloses each of the features recited in the present claims, including the reaction conditions relating to pH, concentration, and reaction and drying temperatures. However, as discussed below, this combination of references does not render the presently claimed invention obvious.

As discussed above, Zhao discloses cross-linked polysaccharides having multiple types of cross-linkages. The “advantages” said to be conferred by the process disclosed by Zhao relate only to hyaluronic acid (HA) having multiple types of cross-linkages (page 4, lines 19-20). Also, according to the description on page 13, line 26 to page 5, line 4, a product resulting from the process disclosed by Zhao:

...“has a greater degree of cross-linking, that is to say, a denser network of cross-links than does single cross-linked HA. A higher degree of cross-linking has been found to reduce the water absorption capacity of the cross-linked HA, resulting in greater stability in aqueous solution. In addition double cross-linked HA has been found to exhibit greater stability against degradation by hyaluronidase, and against degradation due to free radicals, indicating an increased biostability.”

Therefore, in view of Zhao, a person skilled in the art would understand that multiple cross-linkages are required to achieve the stated advantages and Zhao therefore teaches away from the use of a single type of cross linkage as presently claimed. According to M.P.E.P. §2143.01 (V), “if [a] proposed modification would render the prior art invention being modified

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unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984).” In the present case, based upon the emphasis of double cross-linked HA and its advantages by Zhao, one skilled in the art would believe that modification of the multiple cross-linkages with a single type of cross-linkage would be significantly less stable to degradation by hyaluronidase, and therefore would render the invention of Zhao unsatisfactory for its intended purpose.

Mälson discloses various reaction conditions for forming cross-linked polysaccharides, but does not disclose or suggest the claimed process involving a cross-linked polysaccharide gel having a single type of cross-linkage. Since Mälson does not teach the information missing from Zhao et al. (i.e., a single type of cross-linkage), the present claims cannot be obvious in view of this combination of references.

In addition, the presently claimed process results in cross-linked polysaccharides having the surprising and advantageous property of being sufficiently cross-linked with a single type of cross-linkage to resist degradation. These advantageous properties are demonstrated by the Examples provided in the originally filed specification. Example 1 on page 10 demonstrates that the inventive process results in cross-linked polysaccharide gels having a single type of cross-linkage. The comparative data on pages 13-16, in particular Table 3 on page 16, shows that the cross-linked polysaccharide gels produced according to the process of the instant invention are more resistant to degradation than are commercially available gels.

As evidence of the unexpected superiority of cross-linked polysaccharide gels having a single type of cross-linkage over commercially available gels, enclosed is a signed Declaration by one of the inventors, Dr. Geoffrey Heber. The Declaration includes additional data comparing polysaccharide gels prepared according to the present claims with the global market-leading products as further evidence of the nonobviousness of the present claims.

These unexpected advantages are neither disclosed nor suggested by Zhao or Mälson, and could not have been predicted based on the teachings of these references, either alone or in combination. These unexpected results would effectively rebut any contention of prima facie obviousness, and strongly support the nonobviousness of the present claims.

In view of the comments presented above, Applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. § 103(a).

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No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, the Applicants are not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. The Applicants reserve the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that the Applicants have made any disclaimers or disavowals of any subject matter supported by the present application.

CONCLUSION

Applicants submit that all claims are in condition for allowance. However, if minor matters remain, the Examiner is invited to contact the undersigned at the telephone number provided below. Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

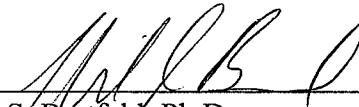
Respectfully submitted,

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Dated: _____

9/22/09

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